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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/667,365	09/21/2000	Masashi Suganuma	12155-002001	9752

7590 03/17/2004

Pillsbury Winthrop LLP
Intellectual Property Group
11682 El Camino Real, Suite 200
San Diego, CA 92130-2593

EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/667,365	SUGANUMA ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2004 and 07 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *82,83 and 85-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *82,83 and 85-87* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20040220* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

The supplemental amendment filed February 20, 2004 is acknowledged and has been entered. The supplemental amendment corrects the deficiency of the prior non-compliant amendment filed October 7, 2003, which was submitted following the interview of October 6, 2003 in response to the final Office action mailed July 14, 2003.

Upon consideration of the amendment filed February 20, 2004, together with consideration of Applicant's remarks of the amendment filed October 7, 2003, the rejection of claims 81-86 under 35 USC § 112, first paragraph set forth in the Office action mailed July 14, 2003 has been withdrawn.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert Bedgood on February 20, 2004.

The application has been amended as follows:

1-81. (Canceled)

82. (Currently Amended) The method of claim [81] 87, wherein the [amount of] DNA content of the cells is measured by FACS analysis using propidium iodide [and FACS analysis].

83. (Currently Amended) The method of claim [81] 87, wherein the [amount of] DNA content of the contacted cells is measured after the cells have been

cultured in the presence or absence of the test compound or polypeptide for a period of about 10 to about 72 hours [after the contacting step (c)].

84. (Canceled)

85. (Currently Amended) The method of claim [84] 87, wherein the [M phase checkpoint activator] agent that specifically arrests the cell cycle at the M phase is colchicine or nocodazole.

86. (Currently Amended) The method of claim [81] 87, wherein the DNA damaging agent or treatment is selected from the group consisting of 5-fluorouracil [(5-FU)], rebeccamycin, doxorubicin, bleomycin, cisplatin, hyperthermia, UV irradiation, and [or] gamma-irradiation.

87. (Newly Added) A method for screening for compounds capable of specifically inhibiting or abrogating the G2 cell cycle arrest checkpoint comprising the following steps:

(a) providing a test compound;

(b) providing the polypeptide of SEQ ID NO: 1897, which polypeptide is capable of inhibiting or abrogating the G2 cell cycle arrest checkpoint and acts as a G2 checkpoint inhibiting positive control;

(c) providing isolated G1 checkpoint impaired cells;

(d) contacting a first sample of said G1 checkpoint impaired cells with a DNA damaging agent or treatment to activate the G2 phase cell cycle arrest checkpoint;

(e) contacting a second sample of said G1 checkpoint impaired cells with an agent that specifically arrests the cell cycle at the M phase;

(f) culturing a portion of said first and second samples of contacted cells in the presence or absence of the test compound;

(g) culturing a portion of said first and second samples of contacted cells in the presence or absence of the polypeptide;

(h) measuring DNA content of said portions of contacted cells cultured in the presence or absence of the test compound or polypeptide to determine the fraction of the cells in the G2 and M phases of the cell cycle;

(i) identifying the test compound as capable of specifically inhibiting or abrogating the G2 cell cycle arrest checkpoint if:

(1) the fraction of the portion of said first sample of contacted cells cultured in the presence of the test compound determined to be in the G2 phase of the cell cycle decreases relative to the fraction of the portion of said first sample of contacted cells cultured in the absence of the test compound determined to be in the G2 phase of the cell cycle; and

(2) the fraction of the portion of said second sample of contacted cells cultured in the presence of the test compound determined to be in the M phase of the cell cycle does not differ significantly from the fraction of the portion of said second sample of contacted cells cultured in the absence of the test compound determined to be in the M phase of the cell cycle;

wherein the identification is validated by the positive control if:

(1) the fraction of the portion of said first sample of contacted cells cultured in the presence of the polypeptide determined to be in the G2 phase of the cell cycle decreases relative to the fraction of the portion of said first sample of contacted cells cultured in the absence of the polypeptide determined to be in the G2 phase of the cell cycle; and

(2) the fraction of said contacted cells cultured in the presence of the polypeptide determined to be in the M phase of the cell cycle does not differ significantly from the fraction of said contacted cells cultured in the absence of the polypeptide determined to be in the M phase of the cell cycle.

This application is in condition for allowance except for the following formal matters:

Applicant has made a claim for foreign priority under 35 USC § 119(a)-(d) or (f), but has not yet complied with the requirements set forth under said statute, because certified copies of the foreign priority documents have not been received.

Therefore, in reply to this Office action, Applicant must provide certified copies of Japanese Patent Application 11-269398 filed September 22, 1999 and Japanese Patent Application 11-340322 filed November 30, 1999.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
March 10, 2004

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600